

# Military Medical Research News

Vol. 4, Issue 1 • January 2017

## Repository, diagnostic center faces time's toll Joint Pathology Center fights for lives, amid materials loss

by Paula Amann

In a rambling brick building, tiny cardboard boxes within poster-sized ones cram the shelves of a vast stockroom that once served as a military laundry. The floor-to-ceiling boxes store some 32 million half-inch wax blocks with tissue from human patients and animals.

A smaller building a few blocks away safeguards more than 50 million laboratory slides, ranged in table-sized trays that move up and down like elevators, at the touch of a console.

This is the Joint Pathology Center, or JPC, a resource for today's researchers and patients, though its collection goes back a century. Over just the past year, materials here have helped investigators from Walter Reed Bethesda explore how compression shapes cartilage, how nasal cancer grows and how military working dogs scar.

"It's fascinating, the wealth of knowledge here," said the center's director, Army Col. Clayton D. Simon interviewed at the JPC's warehouse last month, noting, "There's nowhere else in the world where you can get these cases."

Besides helping researchers, the center's staff of 30 pathologists each year fields more

than 16,000 inquiries for "second opinions" on patients, both active-duty military and veterans.

"We normally get the really difficult cases," said Francisco "Frank" Rentas, the center's director of research, education and tissue repository operations.

Yet, amid the silent stacks of boxes and their bustling custodians, a threat is lurking. Despite the staff's best efforts, time and summer heat are slowly but inexorably damaging the tissue bank.

**See REPOSITORY, page 4**



**Army Col. Clayton D. Simon, director of the Joint Pathology Center, points out cracks encroaching on a digitized slide of heart muscle tissue. The center holds over 50 million laboratory slides dating back to 1917, for use by pathologists and researchers. (Photo by Paula Amann)**

# DEPARTMENT OF RESEARCH PROGRAMS



**Army Col. Peter Weina, director of Department of Research Programs (official photo)**

The Department of Research Programs (DRP) at Walter Reed National Military Medical Center supports research activities in the National Capital Region (NCR) through regular news.

This monthly newsletter covers events, research and administrative policies and procedures, research studies and collaborations, department operations, workshops and other NCR initiatives.

## MILITARY MEDICAL RESEARCH NEWS

### Supervising Editors

Army Col. Ann Nayback-Beebe

### Editor

Paula Amann

### Contributing photographer

John Fadoju

This newsletter appears monthly. We welcome your story ideas, comments, corrections and photographs (action shots are best). Please send any timely information by the 15th day of the prior month for the following month's issue. Send your ideas, pictures or infographics to [paula.m.amann.ctr@mail.mil](mailto:paula.m.amann.ctr@mail.mil).

## RESEARCH FIRST STEPS

Our protocol navigators are available to help you start the process and assist you with your submission. To make an appointment with a protocol navigator, please call the Department of Research Programs (DRP) office at 301-295-8239. DRP is located in Building 17B, third floor, to the left of elevators.

## RESEARCH ROUNDTABLE SCHEDULE

### Walter Reed National Military Medical Center

**America Building (Building 19), Second floor, Room 2301**

- ◆ Tuesday, Jan. 24, 1200-1300
- ◆ Tuesday, Feb. 21, 1200-1300
- ◆ Tuesday, March 21, 1200-1300

Did you miss the last roundtable on applying for research funding at the National Institutes of Health? Please see story and a preview of our next presentation on page 6.

## Contents

<b>New Research Training Mandate .....</b>	<b>3</b>
<b>Department Download .....</b>	<b>5</b>
<b>Research Roundtable .....</b>	<b>6-7</b>
<b>Goodbye and Good Luck, Mr. Simms.....</b>	<b>7</b>
<b>MERF and CITI Courses .....</b>	<b>8</b>
<b>Darnall Library Classes .....</b>	<b>9</b>
<b>Recent Publications .....</b>	<b>9-11</b>
<b>Web Resources .....</b>	<b>12</b>
<b>Training Calendar for EIRB .....</b>	<b>13</b>
<b>Research and Innovation Month .....</b>	<b>14</b>

## EIRB TIP OF THE MONTH

### Fielding the unforeseen

Any seasoned investigator knows this truth: There are protocols, and then there is research as it unfolds in real time.

Wondering how to handle a reportable event that doesn't meet the bar for immediate reporting? At the time of your continuing review, upload an Adverse Event and Deviation Log in the continuing review submission. You can skip a separate Reportable Event Submission Form.

If you have found a great shortcut for working in EIRB, we'd love to hear about it. Please send your solution to [paula.m.amann.ctr@mail.mil](mailto:paula.m.amann.ctr@mail.mil). We will route it to your friendly, local IRB office.

Thanks again for your patience during the transition to EIRB. Meanwhile, our best wishes for success in your research and for a great New Year.



# Research ethics training a new must

The Office of the Under Secretary of Defense (Personnel & Readiness), or OUSD (P&R), has set a new bar for research training. Researchers at Walter Reed National Military Medical Center and their collaborators now have a course of 12 short modules, Responsible Conduct of Research, which they must take.

To meet DoDI 3210.7 requirements for “Research Integrity and Misconduct,” OUSD (P&R) offers RCR training for researchers through the Collaborative Institutional Training Initiative, or CITI.

According to OUSD (P&R), the training is part of a broader plan to foster research integrity. The new required course supplements – but does not replace – the current required course on human subjects protection.

The National Institutes of Health define responsible conduct of research, or RCR, as “the practice of scientific investigation with integrity.” Doing research this way means knowing and applying professional norms and ethical principles throughout the research process, according to the NIH.

Federal mandates drive RCR training requirements, specifically for those receiving federal funding, according to the Institute of Medicine National Research Council. In addition, the Institute of Medicine asserts RCR training is needed to inform ethical decision-making and maintain a culture of high ethical standards among individuals and institutions.

Meanwhile, the Research Regulatory Oversight Office provides policy guidance (PG-03-001) for meeting the minimum education requirement framework (MERF). This role-based training covers the regulatory and ethical principles protecting the rights and welfare of volunteer participants.

Policy Guidance (PG-03-001) requires researchers working with human subjects to meet the MERF by taking the required modules through the CITI program. To start your role-based training, please contact Lisa Thompson, supervisory medical education specialist, at [lisa.p.thompson5.civE@mail.mil](mailto:lisa.p.thompson5.civE@mail.mil).

*— adapted from material provided by Lisa Thompson*

## DEPARTMENT OF RESEARCH PROGRAMS ANNOUNCEMENTS

### Competition deadlines this month!

By now, you may be nearly done applying for competitions set for 2017 Research and Innovation Month. This year the Department of Research Programs (DRP) is sponsoring six different competitions. Abstracts are due by the end of this month, January 30.

Next May 1-5, the Arrowhead Zone will be bursting with posters – from research and case reports to quality improvement, evidence-based practice, and family- and patient- centered care. Will one of those posters be yours? And will you be a finalist or winner in an expanded field of competitions?

Be a research hero – and more. Please join us for all the events of Research and Innovation Month. For more on key dates, competition rules, categories and application, please see back cover or go to DRP’s SharePoint site (see details below).

### Inside our SharePoint

Have you visited the DRP Intranet site recently? This SharePoint site is your one-stop shop for the latest research announcements and more. Check out our rotating banner, staff directory, calendar, competition details and past newsletters.

On the Walter Reed Intranet Site Homepage, under Quick Links, click Education Training and Research under Directorates. Then click on Research. Or click on this link: <https://www.wrnmcc.intranet.capmed.mil/EducationTrainingResearch/ResearchProgramsDepartment/SitePages/Home.aspx>.





## REPOSITORY, from page 1

Temperatures over 80 degrees Fahrenheit soften the paraffin blocks, and some of the slide samples are developing cracks that eventually will destroy them, Simon explained. Less than one percent of the tissue bank, he estimates, is now in digital form.

“We’d like to digitize a lot more,” said Simon, the center’s director.

The U.S. Congress, says Simon, gave him and his predecessors the mandate to modernize the repository. Funds, however, fall short of the task. To digitize the entire collection, estimates Simon, would cost \$190 million.

Housed in a total of five buildings at three military bases near Washington, D.C., JPC safeguards more than medical evidence from generations of service members. Close to 70 percent of its materials, says Simon, came from the civilian world and from abroad, though now it only takes new materials from the Veterans Administration and the military sector.

The collection has its roots in 1862, during the throes of the U.S. Civil War, when Army Surgeon General, Brigadier General William Hammond, led the creation of the Army Medical Museum to gather specimens taken from soldiers during surgery and other medical treatments.

From the start, the museum’s founders shared its collection for study. Over nearly nine decades, the original institution endured.

Shortly after World War II, in 1949, it transformed into the Armed Forces Institute of Pathology. This new institution hired a staff of pathologists, as it grew a collection of tissue samples from across the world.

In 1990, Base Realignment and Closure led the Defense Department to close 27 health care centers. As a result, the institute gained more material, as it received specimens from those facilities.

Some two decades onward, in 2011, further retrenching morphed the institute into JPC, which now offers its diagnostic services only to the military, the U.S. Department of Veterans Affairs and other federal facilities.

Over the years, the center has culled its huge collection, shifting Civil War and other pre-1917 materials to the nearby National Museum of Health and Medicine.



**Francisco “Frank” Rentas, the director of research, education and tissue repository operations at the Joint Pathology Center, pulls a laboratory slide from 1944 in one of the center’s five buildings.**

Today, calls for diagnoses still flood JPC’s phone lines and a wide array of research finds data in its stacks. An in-house study by Drs. Teri Franks and Michael Lewin-Smith is gauging the impact of deployments to Iraq and Afghanistan on the development of lung injury in service

**See REPOSITORY, page 5**



**Anula Bhusry, repository supervisor, demonstrates the console that lifts and lowers shelves of laboratory specimens like these at the Joint Pathology Center. (Photos by Paula Amann)**



## DEPARTMENT DOWNLOAD

### NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS

December's meeting of the Department of Research Programs (DRP) reflected the brisk pace of activity among its various teams. For instance, the flood of requests for determinations – decisions as to whether given projects are research, quality improvement or something else – has led the department to boost the number of staff in this area.

Now joining Dr. Sanjur Brooks, our program manager for human research protections, are three new determinations officers: Public Health Service Cmdr. Mark Miller, a regulatory review officer in the Office of Compliance of the U.S. Food and Drug Administration; Dr. Wendy Bernstein, a staff member of the Hematology/Oncology Department at Walter Reed Bethesda; and Angela Drago, research support specialist for DRP.

Brooks also highlighted two recent policies issued by the department. In November, DRP released Memorandum 2.5, "Professional Misconduct in Research," which outlines ethical pitfalls for researchers. Examples range from misappropriation of data to its misrepresentation. The department also published "General Framework for Post-Approval Compliance Monitoring," which charts the elements of quality assurance and the steps taken by monitors.

For the full text of both policy documents, interested readers may check the DRP intranet under DRP policies and procedures. Or readers may visit this link: <https://www.wrnmmc.intranet.capmed.mil/EducationTrainingResearch/ResearchProgramsDepartment/DRP%20Policy%20and%20Procedure/Forms/AllItems.aspx>

Returning from a leave of absence, Army Col. Ann Nayback-Beebe, DRP's deputy chief, noted a "lighter feeling" among staff members when it comes to the electronic Institutional Review Board. She pointed to improvements in the EIRB as system designers strengthen its features and increase its speed.

"We're leading the charge," said Nayback-Beebe, in a hat tip to the department and its community of researchers for test-driving the online management system. □



**The Joint Pathology Center's director, Col. Clayton Simon, discusses the challenge of preserving its vast warehouse of specimens. Research partners who tap this collection range from the Bill and Melinda Gates Foundation to Google, the National Institutes of Health, the University of Zurich and Walter Reed Bethesda. (Photo by Paula Amann)**

#### REPOSITORY, from page 4

members. Meanwhile, Simon is working with researchers to build an algorithm that would help computers assist pathologists for some diagnoses.

Before any investigators can tap the stores of JPC, its Research Program Management Offices steers them through the process, consulting with the Institutional Review Board of record at Walter Reed Bethesda. JPC staff also double-checks any relevant research agreements with the business office at the Department of Research Programs.

"We work very closely with DRP to make sure we do things by the book," Rentas said, noting that regulations dictate that JPC staff strip all outgoing data of personal identifying information. "All of that is removed before it goes out of the building."

For Simon and his staff, the potential for new research is as tantalizing as a holiday feast. He flags the troves of tissue from 1920s bladder tumors, specimens from African epidemics of the late 20th century, and somewhere in the stacks, second opinions from pathologists on what was once a deadly disease: AIDS.

With work and patience, a new generation of researchers could unlock their secrets, while they remain. □





# RESEARCH ROUNDTABLE

## A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson

The Department of Research Programs (DRP) would like to offer a 10-15 minute presentation to your staff on DRP services, upcoming events and policy updates from the Office of the Under Secretary of Defense [(Personnel & Readiness and Research Regulatory Oversight Office (R202)], a review of the Minimum Education Requirements Framework (MERF) issued by the Office of the Assistant Secretary of Defense for Research and Engineering, and information on required Collaborative Institutional Training Initiative (CITI) training. We would like to join you once annually or every six months, before or after your program meets for didactic or lecture hall sessions.

Our goal is to promote research. We want to help familiarize your Graduate Medical Education (GME) trainees, faculty, and staff with DRP services to help them meet their research and scholarly project program requirements. Our services include assistance with protocol development, courses on research methods, statistics, and grant writing, GME trainee research project funding opportunities, collaborative agreements development, manuscript editing, publication clearance, and bench research space through our Biomedical Research Laboratory.

DRP invites you to join us at the Research Roundtable on the third Tuesday of every month. On Jan. 24, I will discuss research MERF and CITI training

We invite you to present as well. If there is a pressing concern you would like addressed or if you would like to present material on a topic of your choice, please talk to me at the Research Roundtable or send an email to [lisa.p.thompson5.civ@mail.mil](mailto:lisa.p.thompson5.civ@mail.mil).



**Lisa Thompson,**  
supervisory medical  
education specialist  
(Photo by subject)

## Seeking funds, protecting human subjects Roundtable offers view from National Institutes of Health

by Paula Amann



**Petrice Brown-Longenecker, a human research protection officer with the Office of Extramural Programs at the National Institutes of Health, addresses the Dec. 20 Research Roundtable. Her agency asks grant applicants for clinical trials to make a Data and Safety Monitoring Plan, among several requirements. (Photo by Paula Amann)**

At the core of human subjects protection is a complex federal regulation with a simple name: the Common Rule. Also known by its formal name, 45 CFR part 46, the provision underlies applications for grants for research at the National Institutes of Health.

“This is the law, and we all have to follow the law, if we do research,” said Petrice Brown-Longenecker, a human research protection officer with the NIH Office of Extramural Programs, in remarks to the Research Roundtable on Dec. 20.

In addition, NIH has several of its own requirements for grants to human subjects research, the speaker noted. For clinical trials, the agency asks for a Data and Safety Monitoring Plan as a separate attachment.

“The riskier the study, the more data you’re going to give in your DSMP,” Brown-Longenecker said.

NIH also requires registration in [clinicaltrials.gov](http://clinicaltrials.gov). For NIH-defined clinical research, researchers must make plans to include women,

**See FUNDS, page 7**



## FACES OF RESEARCH

### GOODBYE AND GOOD LUCK

James Simms' engaging smile has brightened the Department of Research Programs, where he has worked as publications clearance staff, for the past four years. Before that, Simms served as a librarian at the Darnall Medical Library at the Walter Reed Bethesda.

Simms took an unusual route to a career amid book stacks and later, online catalogs. As a Benedictine monk in Minnesota, he earned a college degree while working in the monastery library. After 11 years in the order, Simms opted to explore the world beyond. Married three years later, he embarked

on a varied career in and around libraries.

A highlight was his eight years at NPR, cataloguing the radio network's interviews and the bursts of music played between news segments. Simms served such radio personalities as Susan Stamberg, Linda Wertheimer and Bob Edwards, recalling them as "extremely nice people to work with." Later, in the early days of computers, Simms would go on to digitize a corporate library during his 15-year stint with Washington Gas.

In retirement, Simms plans to step up his volunteer food deliveries to low-income elderly people with disabilities in Washington, D.C. "I'll do it as long as I can," Simms said. "I'm 78, and I can do it."



**James Simms at ease in his office at the Department of Research Programs (Photos by John Fadoju)**



**Army Col. Ann Nayback-Beebe, deputy chief of the Department of Research Programs, presents James Simms with a decorated hospital blanket at his farewell on Dec. 21.**

---

## FUNDS, from page 6

minorities and children, as well as creating planned enrollment tables.

Finally, NIH requires a single Institutional Review Board, or IRB, of record for multi-site research projects, the speaker stressed.

As for the Common Rule, Brown-Longenecker walked the roundtable audience through the way her agency applies it in grant applications.

"Just because your study involves human stuff doesn't mean it involves human subjects," Brown-Longenecker said.

For the purposes of NIH funding, she stressed, human subjects are living people about whom a researcher gets data in one of three ways: intervention, interaction and identifiable private information.

When NIH looks at grant applications for human subjects research, they are scanning for four key criteria, Brown-Longenecker said. Reviewers assess relative risks, adequacy

of protections, potential benefits and the significance of possible findings.

Brown-Longenecker asked her audience to picture a committee of people meeting in a hot room to wade through NIH grant applications.

"Everything you need to tell them has to be in your application," Brown-Longenecker said.

That awards committee across Rockville Turnpike cannot make assumptions about what the applicant might intend. Indeed, lack of clarity can result in a lagging award, she emphasized.

The human subjects section of an NIH application does not follow a formula, Brown-Longenecker noted. In fact, each study follows a different contour.

For example, one project may face a delayed onset, because of delays in recruiting subjects. What's more, applicants must plan protection of human subjects that matches the scope of risk in the proposed study. □





# TRAINING FOR RESEARCHERS



The Department of Research Programs works to promote research and protect human participants. We offer training workshops for researchers in two key areas:

- ▣ Collaborative Institutional Training Initiative (CITI)
- ▣ Minimum Educational Requirement Framework (MERF)

The MERF workshop will help you and your research team learn policy guidelines, requirements for meeting the MERF, and training modules needed for your investigative roles.



## MERF AND CITI TRAINING



### WORKSHOP SCHEDULE

Join monthly workshops on MERF and CITI. Ms. Lisa Thompson, M.S.H.A., M.B.A., will share the latest policy guidance from the Research Regulatory Oversight Office within the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD [P&R]). The workshop will cover the following vital areas:

- ▣ OUSD (P&R) Assurance for the Protection of Human Subjects
- ▣ Minimum Education Requirements Framework (MERF) for DoD Personnel involved In Human Subjects Research
- ▣ Collaborative Institutional Training Initiative (CITI): Role-based training for researchers who conduct, review or approve research with human subjects in compliance with the MERF standards set forth by the Assistant Secretary of Defense for Research and Engineering

You can arrange training in your department. Or join our monthly classes in the rooms listed below (eight seats are available). Please email or call to reserve your seat. Questions? Please contact Ms. Lisa Thompson at 301-295-8231 or [lisa.p.thompson5.civ@mail.mil](mailto:lisa.p.thompson5.civ@mail.mil).

### CLASSES IN HEROES BUILDING (BUILDING 5), FOURTH FLOOR:

- ▣ February 13, 2-3 p.m., Computer Classroom 1 (4010)
- ▣ March 13, 2-3 p.m., Computer Classroom 2 (4011)
- ▣ April 10, 2-3 p.m., Computer Classroom 2 (4011)
- ▣ May 8, 2-3 p.m., Computer Classroom 2 (4011)



**YOU BELONG IN THE CITI. START TRAINING TODAY!**





# DARNALL MEDICAL LIBRARY

## Research and Scholarly Communication Support

Lyubov Tmanova, DVM, MLIS, MS, the informationist/biomedical research librarian, offers research support to the WRNMMC biomedical community and helps integrate biomedical information into medicine in order to advance research and scholarly communication. Research-oriented classes are offered on a quarterly basis. Individual and group consultations are available upon request.

### 2016 Research and Scholarly Communication Classes

#### CLASSES

##### Preparing a Manuscript for Publication

Library: Darnall Medical Library

Location: Building 19, Room 2301

Instructor: Dr. Tmanova

When: Tuesday, Jan. 10, 2017 at 1300 to 1400

To register, go to the website below. For individual consultations, contact the instructor.

Contact: **Lyubov Tmanova, DVM, MLIS, MS**  
Informationist / Biomedical Research Librarian

**Darnall Medical Library, Building 1, Room 3458**

Phone: 301-319-2475

Email: lyubov.tmanova.civ@mail.mil

Website: [www.wrnmmc.libguides.com/home/researchsupport](http://www.wrnmmc.libguides.com/home/researchsupport)

##### Preparing a Manuscript for Publication

Library: Darnall Medical Library

Location: Building 19, Room 2301

Instructor: Dr. Tmanova

When: Tuesday, Feb. 14, 2017 at 1300 to 1400

## RECENT PUBLICATIONS

### Courtesy of Darnall Medical Library

Find articles by authors at Walter Reed Bethesda in bold.

Abbara S, Blanke P, Maroules CD, et al. [SCCT guidelines for the performance and acquisition of coronary computed tomographic angiography: a report of the society of Cardiovascular Computed Tomography Guidelines Committee: Endorsed by the North American Society for Cardiovascular Imaging \(NASCI\)](#). *J Cardiovasc Comput Tomogr*. 2016;10(6):435-449. Walter Reed Bethesda author: **Villines T**

**Andrews AM**, Deehl C, Rogers RL, **Pruziner AL**. [Core temperature in service members with and without traumatic amputations during a prolonged endurance event](#). *Mil Med*. 2016;181(S4):61-65.

**Balazs GC**, **Dworak TC**, Tropf J, **Nanos GP 3rd**, **Tintle SM**. [Incidence and risk factors for volar wrist ganglia in the U.S. military and civilian populations](#). *J Hand Surg Am*. 2016;41(11):1064-1070.

**Bernstein JG**, Danielsson H, Hällgren M, Stenfelt S, Rönnerberg J, Lunner T. [Spectrotemporal modulation sensitivity as a predictor of speech-reception performance in noise with hearing aids](#). *Trends Hear*. 2016 Nov 4;20.?

Blakely WF, Romanyukha A, Hayes SM, et al. [U.S. Department of Defense multiple-parameter biodosimetry network](#). *Radiat Prot Dosimetry*. 2016 Nov 24. [Epub ahead of print] Walter Reed Bethesda author: **Reyes RA**

**Chen YT**, Williams L, **Zak MJ**, Fredericson M. [Review of ultrasonography in the diagnosis of carpal tunnel syndrome and a proposed scanning protocol](#). *J Ultrasound Med*. 2016;35(11):2311-2324.

See PUBLICATIONS, page 10



## PUBLICATIONS, from page 9

- Cunningham R, Kemp J, Sperling L. [Another tattoo reaction pitfall: a pink lamb in wolf's clothing.](#) *JAMA Dermatol.* 2016 Nov 23. [Epub ahead of print]
- Daemen MJ, Ferguson MS, Gijzen FJ, et al. [Carotid plaque fissure: an underestimated source of intraplaque hemorrhage.](#) *Atherosclerosis.* 2016;254:102-108. Walter Reed Bethesda author: **Demarco K**
- Fairbairn NG, Ng-Glazier J, Meppelink AM, et al. [Erratum: light-activated sealing of acellular nerve allografts following nerve gap injury.](#) *J Reconstr Microsurg.* 2016;32(9):e1. Walter Reed Bethesda authors: **Valerio IL, Fleming ME**
- Fentanes E, Wessman D, **Villines TC**, Steel KE. [Serving to heal and honored to serve: an insight into military cardiovascular fellowship.](#) *J Am Coll Cardiol.* 2016;68(19):2118-2121.
- Formby PM**, Kang DG, **Helgeson MD**, **Wagner SC**. [Clinical and radiographic outcomes of transforaminal lumbar interbody fusion in patients with osteoporosis.](#) *Global Spine J.* 2016;6(7):660-664.
- Glaser JJ, **Cardarelli C**, Galvagno S Jr, Scalea TM, Murthi SB. [Bridging the gap: hybrid cardiac echo in the critically ill.](#) *J Trauma Acute Care Surg.* 2016;81(5 Suppl 2 Proceedings of the 2015 Military Health System Research Symposium):S157-S161.
- Heitmann RJ**, Weitzel RP, Feng Y, Segars JH, Tisdale JF, Wolff EF. [Maternal T regulatory cell depletion impairs embryo implantation which can be corrected with adoptive T regulatory cell transfer.](#) *Reprod Sci.* 2016 Nov 9. [Epub ahead of print]
- Hulten E**, Blankstein R, Di Carli MF. [The value of noninvasive computed tomography derived fractional flow reserve in our current approach to the evaluation of coronary artery stenosis.](#) *Curr Opin Cardiol.* 2016;31(6):970-976.
- Isaacson BM, **Hendershot BD**, Messinger SD, et al. [The center for rehabilitation sciences research: advancing the rehabilitative care for service members with complex trauma.](#) *Mil Med.* 2016;181(S4):20-25. Walter Reed Bethesda authors: **Pruziner AL, Dearth CL, Cohen SP, Pasquina PF**
- Jackson DO, **Byrd K**, Vreeland TJ, et al. [Interim analysis of a phase I/IIa trial assessing E39+GM-CSF, a folate binding protein vaccine, to prevent recurrence in ovarian and endometrial cancer patients.](#) *Oncotarget.* 2016 Nov 11. [Epub ahead of print]  
Walter Reed Bethesda authors: **Conrads TP, Darcy KM, Hamilton CA, Maxwell GL**
- Jenkins DH, **Bailey JA**. [Origins and importance of the joint trauma system.](#) *J Trauma Acute Care Surg.* 2016;81(5 Suppl 2 Proceedings of the 2015 Military Health System Research Symposium):S75-S76.
- Kassop D**, Nam JJ, Cebula BR, et al. [A tale of two diagnoses: The role of noninvasive cardiovascular imaging to differentiate cardiac amyloidosis.](#) *J Nucl Cardiol.* 2016 Nov 8. [Epub ahead of print] Additional Walter Reed Bethesda author: **Hulten EA**
- Kwok RM**, Tran TT. [Hepatitis B and risk of non-hepatocellular carcinoma malignancy.](#) *Clin Liver Dis.* 2016;20(4):693-702.
- Little DJ**, **Deressa WT**, **Watson MA**, **Yuan CM**. [Metabolically healthy obesity and development of chronic kidney disease.](#) *Ann Intern Med.* 2016;165(10):743-744.
- Liu R**, **Kurihara C**, Tsai HT, et al. [Classification and treatment of chronic neck pain: a longitudinal cohort study.](#) *Reg Anesth Pain Med.* 2016 Nov 14. [Epub ahead of print] Additional Walter Reed Bethesda authors: **Silvestri PJ, Cohen SP, Pasquina PF**
- Lu R, Munroe ME, Guthridge JM, et al. [Dysregulation of innate and adaptive serum mediators precedes systemic lupus erythematosus classification and improves prognostic accuracy of autoantibodies.](#) *J Autoimmun.* 2016;74:182-193. Walter Reed Bethesda author: **Keith MP**
- Mann-Salinas EA, Le TD, Shackelford SA, et al. [Evaluation of role 2 \(R2\) medical resources in the Afghanistan combat theater: initial review of the joint trauma system R2 registry.](#) *J Trauma Acute Care Surg.* 2016;81(5 Suppl 2 Proceedings of the 2015 Military Health System Research Symposium):S121-S127. Walter Reed Bethesda author: **Bailey JA**
- Mesfin A, Li X, Dickens JF, Alolabi B, Miller AN. [The 2015 AOA North American traveling fellowship.](#) *J Bone Joint Surg Am.* 2016;98(22):e100.
- Miller CR, Chappell NP, Sledge C, et al. [Are different methotrexate regimens as first line therapy for low risk gestational trophoblastic neoplasia more cost effective than the dactinomycin regimen used in GOG 0174?](#) *Gynecol Oncol.* 2016 Nov 2. [Epub ahead of print] Walter Reed Bethesda authors: Phippen NT

See PUBLICATIONS, page 11



## PUBLICATIONS, from page 10

Munroe ME, Lu R, Zhao YD, et al. [Altered type II interferon precedes autoantibody accrual and elevated type I interferon activity prior to systemic lupus erythematosus classification.](#) *Ann Rheum Dis.* 2016;75(11):2014-2021. Walter Reed Bethesda author: **Keith MP**

**Nadolsky KZ.** [Cystatin C, diabetic kidney disease and implications for diabetes management.](#) *Endocr Pract.* 2016 Nov 16. [Epub ahead of print]

Pan Q, Jampel HD, Ramulu P, et al. [Clinical outcomes of gamma-irradiated sterile cornea in aqueous drainage device surgery: a multicenter retrospective study.](#) *Eye (Lond).* 2016 Nov 11. [Epub ahead of print] Walter Reed Bethesda author: **Cute D**

Rungruang BJ, Miller A, Krivak TC, et al. [What is the role of retroperitoneal exploration in optimally debulked stage IIIC epithelial ovarian cancer? An NRG Oncology/Gynecologic Oncology Group ancillary data study.](#) *Cancer.* 2016 Nov 16.[Epub ahead of print]  
Walter Reed Bethesda author: **Hamilton CA**

**Schnall BL, Chen YT, Bell EM, Wolf EJ, Wilken JM.** [Functional outcomes of service members with bilateral transfemoral and knee disarticulation amputations resulting from trauma.](#) *Mil Med.* 2016;181(S4):55-60.

**Shedlock K, Susi A, Gorman GH, Hisle-Gorman E, Erdie-Lalena CR, Nylund CM.** [Autism spectrum disorders and metabolic complications of obesity.](#) *J Pediatr.* 2016;178:183-187.e1.

**Sheffield B, Brungart D, Tufts J, Ness J.** [The effects of elevated hearing thresholds on performance in a paintball simulation of individual dismounted combat.](#) *Int J Audiol.* 2016 Nov 22:1-7. [Epub ahead of print]

Thinggaard E, Kleif J, Bjerrum F, et al. [Off-site training of laparoscopic skills, a scoping review using a thematic analysis.](#) *Surg Endosc.* 2016;30(11):4733-4741. Walter Reed Bethesda author: **Ritter EM**


**Villines TC, Peacock WF.** [Safety of direct oral anticoagulants: insights from postmarketing studies.](#) *Am J Emerg Med.* 2016;34(11S):9-13.

**Villines TC, Peacock WF.** [Safety of direct oral anticoagulants: insights from postmarketing studies.](#) *Am J Med.* 2016;129(11S):S41-S46.

Vrcek I, **Chou E**, Blaydon S, Shore J. [Wingtip flap for reconstruction of full-thickness upper and lower eyelid defects.](#) *Ophthal Plast Reconstr Surg.* 2016 Nov 2. [Epub ahead of print]

**Wagner SC, Formby PM, Helgeson MD, Kang DG.** [Diagnosing the undiagnosed: osteoporosis in patients undergoing lumbar fusion.](#) *Spine (Phila Pa 1976).* 2016;41(21):E1279-E1283.

**Williams SG, Wickwire EM, York C.** [A snapshot in time: subjective-objective discrepancies during In-lab polysomnography.](#) *J Clin Sleep Med.* 2016;12(11):1437-1438.

Yelskaya Z, Bacares R, Salo-Mullen E, et al. [CDH1 missense variant c.1679C>G \(p.T560R\) completely disrupts normal splicing through creation of a novel 5' splice site.](#) *PLoS One.* 2016;11(11):e0165654. Walter Reed Bethesda authors: **Lehrich DA, Fasaye GA** 





# REGULATORY RESOURCES

*The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked web sites, or the information, products or services contained therein. For other than authorized activities such as military exchanges and Morale, Welfare and Recreation (MWR) sites, the U.S. Department of Defense does not exercise any editorial control over the information you may find at these locations.*

## Education Materials

- [Belmont Report](#)

*The Belmont Report provides “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” that is found in Code of Federal Regulations, 45 CFR part 46.*

- [Comparison of FDA and HHS Regulations](#)

*The FDA provides a chart comparing FDA's regulations for human subject protection with those of the Department of Health and Human Services.*

- [The President's Council on Bioethics](#)

*This web site provides useful references on ethical issues that arise from advances in biotechnology and biomedical sciences.*

- [Clinical Trials.gov](#)

*Clinical Trials is a service of the National Institutes of Health, provides free public access to a database of Federal and private studies taking place nationwide and provides information on clinical studies for a wide range of diseases and conditions.*

- [HHS Office for Human Research Protections](#)

*HHS OHRP provides assurances and IRB registration, education, policy guidance, and workshops.*

- [HHS Office of Civil Rights](#)

*HHS Office of Civil Rights provides guidance on the Health Insurance Portability and Accountability Act (HIPAA) and Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule).*

- [MedlinePlus](#)

*MedlinePlus provides medical research literature including full-text drug information and an illustrated medical encyclopedia.*

- [Office for Human Research Protections \(OHRP\)](#)

*OHRP Guidebook (1993) provides current and historical materials about human subject protection. Caution: this serve as a guide and some information is obsolete; however, some portions remain valid.*

- [Federal Policy for the Protection of Human Subjects \(Common Rule\)](#)

*HHS provides information about HHS regulations, 45 CFR part 46 and four subparts a, b, c, and d.*

- [Protection of Human Subjects and Adherence to Ethical Standards](#)

*This instruction sets policy and responsibilities for the protection of human subjects in DoD-supported programs to implement part 219 of title 32, Code of Federal Regulations (the Common Rule) .*

- [Protocol Review](#)

*HHS provides guidance for protocol development, use of IRB, and Expedited Review procedures and exemptions.*

- [Informed Consent](#)

*HHS provides informed consent requirements, guidance on the use of exculpatory language, legal obligation and penalties, documentation and changes to documentation.*

- [Investigators](#)

*HHS provides investigators guidance about emergency medical care and research.*

- [Biological Material and Data](#)

*HHS provides guidance and the law about research involving the use of biological material and data.*

- [Vulnerable Populations](#)

*HHS provides guidance for populations including prisoners, children, and HIV human subjects.*

**See RESOURCES, page 14**



*Walter Reed National Military Medical Center*  
*Department of Research Programs*

# **TRAINING FOR ELECTRONIC INSTITUTIONAL REVIEW BOARD (EIRB)**

## **QUESTION AND ANSWER SESSIONS**

***Time slot: Mondays 1200–1300***

<b>Month</b>	<b>Dates</b>
	<i>Radiology Conference Room B015, Building 19, Basement</i>
<b>January</b>	9   23   30
<b>February</b>	6   13   27
<b>March</b>	6   13   20   27



*The Department of Research Programs at  
Walter Reed National Military Medical Center presents*

**2017 RESEARCH AND INNOVATION MONTH**  
*Be a research hero — and more.*

## IMPORTANT DATES

### Call for Abstracts

☐ **01–30 January (abstract submission deadline: 30 January)**

Medical trainees, staff, and faculty register for a research or non-research competition by sending their abstracts and related forms in a single email to [dha.bethesda.wrnmcc.mbx.researchandinnovationmonth@mail.mil](mailto:dha.bethesda.wrnmcc.mbx.researchandinnovationmonth@mail.mil).

### Poster Production

☐ **01–27 February (poster draft submission deadline: 27 February)**

All participants must submit a poster draft to the Medical Graphic Arts Department (MGAD). Points of contact are Mary-Ann Ayrandjian ([mary-ann.ayrandjian.civ@mail.mil](mailto:mary-ann.ayrandjian.civ@mail.mil)) and Shane Stiefel ([shane.m.stiefel.civ@mail.mil](mailto:shane.m.stiefel.civ@mail.mil)).

### Poster Display Week

☐ **01–05 May**

All competition participants display their research posters in the Mezzanine Center, East, and West Wings of Building 9. Posters based on Unity of Effort will carry its logo in the upper right corner. Unity of Effort reflects the partnerships among Walter Reed National Military Medical Center (Walter Reed Bethesda) and its neighbors, the Uniformed Services University of the Health Sciences and the National Institutes of Health.

☐ **03 May – Poster Competition I (Case Reports, Evidence-Based Practice, and Quality Improvement)**

Finalists from non-research competition categories present their posters to judges in Building 9, East Wing. Award ribbons will be pinned next to the winning posters of each research competition category.

☐ **04 May – Poster Competition II (Paul Florentino Patient and Family-Centered Care)**

Quality improvement participants in this category will present their project posters for first, second, and third prizes in Building 9.

### Research Symposia I and II

☐ **09–10 May**

Finalists for the Bailey K. Ashford and Robert A. Phillips research awards present slides on their work before judges in Memorial Auditorium, Building 2, third floor. Winners receive certificates and medallions. Also, winners of Poster Competitions I and II will present.

### 5th Annual Aware for All

☐ **16 May**

Aware for All aims to help the public make informed decisions about clinical research participation through speakers and display tables. Research teams at Walter Reed Bethesda and groups from the National Capital Region showcase their work in the lobby of Building 19.

### Spring Research Summit

☐ **24 May**

Research-related groups present slides, share information, and network about their work at Memorial Auditorium, Building 2, third floor.

**For details on Research and Innovation Month, contact the Department of Research Programs:**  
[dha.bethesda.wrnmcc.mbx.researchandinnovationmonth@mail.mil](mailto:dha.bethesda.wrnmcc.mbx.researchandinnovationmonth@mail.mil)

